

**REMARKS**

Claims 1-30 are all the claims pending in the application. Claims 1, 2, 7 and 8 have been withdrawn from consideration. Claims 3-6 and 9-30 are rejected.

**I. Rejection of claims under 35 U.S.C. §101**

At page 3 of the Office Action, the Examiner rejects claims 3-6 and 9-30 under 35 U.S.C. §101, as lacking utility.

The Examiner refers back to the Office Action dated April 25, 2001, for the basis for this rejection.

Briefly, the Examiner states that Applicants arguments, set forth in the Amendment dated July 25, 2001, have been fully considered but are not deemed to be persuasive for the following reasons:

- 1) The present rejection is in compliance with the most current version of the Patent Office's Utility Guidelines which require that all biological inventions have a real-world utility.
- 2) With regard to Applicants' argument for SREB2 involvement in long-term potentiation, as evidenced by SREB2 activation of CREB, as well as Northern blots showing SREB2 expression in the hippocampus, the Examiner states that there are several problems. First, the Examiner claims that many G-protein coupled receptors make use of CRE/CREB in their transduction cascades, as well as utilize the serum response element SRE. Further, G-protein coupled receptors appear to be generalists in their intracellular cascades, and one would expect that an unknown receptor would likely cause binding and phosphorylation of CRE/CREB after receptor activation. Thus, the Examiner concludes, Applicants' argument that CREB is

important in long-term potentiation (LTP) just points out the fact that CREB phosphorylation is important in numerous biological processes, LTP being just one of them.

3) The argument that SREB2 expression in the hippocampus is evidence that SREB2 is involved in the processes of LTP or LTD is not convincing in light of evidence showing SREB2 expression in almost all tissues of neural origin, as well as the testis.

In response, Applicants again assert that the disclosure of the present application provides a specific, substantial and credible utility for the present invention. Applicants incorporate by reference the arguments they asserted in the Amendment filed July 25, 2001, herein.

In further support of the utility of the present invention, Applicants also enclose herewith a Declaration Under 37 C.F.R. §1.132, prepared and executed by Dr. Jun Takasaki, one of the inventors of the present application.

As stated in the Declaration, Applicants have shown that overexpression of SREB2 contributes to neurodegeneration in the CA3 area neurons and may worsen the “epilepsy” among the central nervous system. Accordingly, the receptor has clear utility as a target for therapeutic agents in the treatment of central nervous system diseases.

As further stated in the Declaration, expression of SREB2 is correlated with Alzheimer’s disease-like symptoms such as memory and learning impairment. Accordingly, the receptor also has clear utility as a target of therapeutic agents for treating central nervous system diseases relating to memory and learning.

In view of the comments above and in the previous Amendment, and the statements of Dr. Takasaki in the enclosed Declaration, Applicants assert that the disclosure of the present application

does provide a specific, substantial and credible utility for the present invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

**II. Rejection of claims under 35 U.S.C. §112**

At page 3 of the Office Action, the Examiner maintains the rejection of claims 3-6 and 9-30 under 35 U.S.C. §112 as not being enabled due to the lack of utility.

In response, Applicants reiterate their assertion that the present invention provides a specific, substantial and credible asserted utility for the invention recited in the claims of the instant application. Furthermore, based on the asserted utility, the skilled artisan would know how to use the claimed invention, and thus the claims are fully enabled.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

**III. Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

RESPONSE UNDER 37 C.F.R. §1.111  
U.S. Appln. No. 09/622,439

Q60438

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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